

Remarks and argument

Applicant thanks the Examiner for the courtesy extended to Applicant's representatives during an in-person interview conducted on April 8, 2007. A copy of the interview summary is hereby attached to this correspondence.

Claims 1-5, 7, 11-12, 16-35, 37-39, 41-43, 45-46, and 55-63 are pending in this application. Claims 1, 55 and 61 are independent.

35, 39 and 43 are amended. The claims were originally presented in a Markush format. Applicant respectfully submits that such formats are generally accepted in Chemical claims. However, in the interest of advancing prosecution, Applicant has deleted part of the claims so that none of the claims is in a Markush format any longer.

Reconsideration is respectfully requested.

I. Rejection under 35 U.S.C. 103(a)

Claims 1-5, 7, 11, 12, 16-35, 37-39, 41-43, 45,46 and 55-60 are rejected under 35 U. S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518.

The claims are drawn to a composition comprising ascorbyl-2-phosphate or a sodium or potassium salt thereof and further comprising calcium ions wherein the composition is mixed with an orally acceptable carrier, and further comprising a calcium chelating agent, a pyrophosphate, tripolyphosphate or polyphosphate tartar control agent, a water soluble fluid, water soluble solid, humectant, thickener, surfactant, sweetener, flavorant, colorant, abrasive, stabilizer, fluoride containing compound, anticaries agent, antimicrobial agent, essential oil and a desensitizing agent.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na^+ , K^+ , Ca^{++} or Mg^+ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. Working example I teaches calcium diphosphate dihydrate (source of calcium/abrasive), sodium carboxymethylcellulose and carrageenan (thickeners), glycerin (water soluble liquid), sorbital (water soluble solid), fragrance (flavor), preservative (antimicrobial), sodium saccharin (sweetener), sodium lauryl sulfate (surfactant), and ascorbic acid magnesium phosphate.

Showa Denko does not teach the desensitizing agents of claims 40-44, it does not teach the non water-soluble solid and liquid and it does not teach the pyrophosphate, tripolyphosphate or polyphosphate tartar control agent.

Pera (4,755,525) teaches strontium desensitizing agent for the teeth (column 5, lines 27-43).

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate desensitizing agents and vegetable oils and wax. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition which is effective in comprehensively cleaning teeth and desensitizing teeth of individuals that have become sensitized. Strontium is a well-known desensitizer, which is known and used in dentifrices as evidenced by the teachings of Pera (4,775,525). Vegetable oil would aid in mixing the dentifrice composition and the wax would effectively coat the teeth and add shine to the teeth.

Parran et al. teach oral compositions containing pyrophosphate salts which provide an anticalculus (aka tartar) benefit (see abstract) and teach the

pyrophosphates salts useful in the invention in an amount of about 1.5% (column 2, lines 28-52) which is encompassed by the claimed 1 % to about 4%.

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the instantly recited tartar control agents. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition, which is effective in comprehensively cleaning teeth and removing tartar. As stated in Parran et al., the pyrophosphate salts provide an anticalculus (tartar control) benefit in dentifrices (see abstract).

Applicant claims a pH of the composition from about 5.5 to about 10.0 now in independent claim 1. However, if applicant wishes to rely on provisional application number 60/263884, for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation. There is no recitation of a pH of from about 5.5 to about 10.

See <http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html> December 1 995 wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values. Thus it would have been obvious to employ a pH of 5.5 to 10 since this range encompasses neutral pH's and this would be most compatible for formulations with fluoride.

Applicant respectfully traverses the rejection.

Showa Denko KK teaches ascorbic acid phosphoric acid ester or its salt (e.g. Na⁺, K⁺ Ca⁺⁺ or Mg⁺ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. The oral composition is in the form of a toothpaste, a chewing gum and troches. However, since calcium diphosphate dehydrate is also taught as an abrasive, large amounts of the phosphate material is used, specifically 45%. There is no teaching of a tartar control agent in the amounts of about 1 to about 4% of the composition in combination with an ascorbyl-2-phosphate compound, or a sodium or potassium salt thereof, at a pH of about 5.5 to about 10.

Pera U.S. Patent No. 4,775,525 is cited by the Examiner to show that a strontium compound can be a desensitizing agent. In addition, Pera essentially teaches away from the use of normal tartar control agents and abrasives. "In general, while no abrasive is harsh enough to remove enamel, some dentifrices may harm cementum and dentin. These products should be avoided by individuals with periodontal disease and hypersensitive teeth. Identifying the different kinds of offending dentifrices is difficult because the interaction of inert ingredients in each formula (which changes over time) may enhance or retard the effect of the abrasive within the mixture. In general, powders are more abrasive than pastes, and products that claim to be tooth whiteners often are harsher than others. Specific abrasive ingredients which may harm dentin include calcium carbonate, anhydrous dibasic calcium phosphate and silica." See Col. 1, line 57 to Col. 2, line 3. (Emphasis added).

Parran et al disclose oral compositions containing soluble pyrophosphate salts which provide an anticalculus (aka tartar) benefit (see abstract) in the amount of at least 1.5 % in addition to "from about 0% to about 70% of a dental abrasive selected from the group consisting silica, alumina, calcium

pyrophosphate, insoluble metaphosphates and thermosetting polymerized resins". See Col. 2, lines 36-55.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Applicant respectfully submits that Showa Denko KK does not teach the invention of claims 1 and 55. There is no teaching of a tartar control agent in the amounts of about 1 to about 4% of the composition in combination with an ascorbyl-2-phosphate compound, or a sodium or potassium salt thereof, at a pH of about 5.5 to about 10 in Showa Denko KK. These deficiencies are not supplied by Pera as Pera is only cited by the Examiner to teach strontium as a sensitivity relief agent. Besides, Pera teaches away from the use of normal tartar control agents and abrasives. Even if it is combinable with Showa Denko, the combined teaching does not lead one of ordinary skill in the art to arrive at the present invention since Pera specifically teaches away from a phosphate tartar control agent.

Nor are the deficiencies supplied by Parran, as noted above.

As for the article of <http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html> December 1995 cited by the Examiner, it may teach what the Examiner notes, i.e., "wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the

abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values", however, the disclosure of a neutral pH does not supply the deficiencies of Showa Denko KK. In addition, the overlapping range as noted by the Examiner, if any, "does not expressly or inherently disclose a claimed range...", as held by the Federal Circuit in *Atofina v. Great Lakes Chemical Corporation*, 441 F.3d 991; 2006 U.S. App. LEXIS 7180; 78 U.S.P.Q.2D (BNA) 1417. In *Great Lake Chemicals*, the Federal Circuit specifically held that the disclosure of a 0.001 to 1.0 percent range "does not expressly or inherently disclose a claimed range of ratios" of 0.1 percent to 5.0 percent, "although there is a slight overlap". *Id.* at 24. Here, the article only mentions a neutral pH. There is clearly no teaching of the pH range recited in the claims.

As for the pH range in claim 1, Applicant respectfully submits that Applicant's claim of a composition having a pH from about 5.5 to about 10.0 in independent claim 1 is fully supported by the provisional application. In the provisional application, the compositions listed on page 3 cover a large range of compositions whose pH is in the range of about 5.5 to about 10. For example, sodium ascorbyl phosphate has a pH of 9-10 at a 3% solution. See <http://www.sciencelab.com/page/S/PVAR/10426/SLS3580>. A 0.4 M solution (1.68%) of sodium fluoride (molecular weight of 42) has a pH 3 to 4. See <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=243760>. Based on these known values, it can be seen that the pH range is about 5.5 to about 10. In addition, Applicant is submitting a 37CFR 1.132 declaration, attached to this response, to show the pH range of actual formulations made in accordance with the ingredient list presented on page 3 of the provisional application. Of the four

formulations made, a range of from 3.5 to 9.1 is obtained. In fact, other pH ranges can be arrived at by picking other ratios of ingredients. Thus, the pH range as claimed is indeed fully supported.

As for claims 55 and 61, Applicant respectfully submits that none of the cited references, alone or in combination, teaches the subject matter of claim 55 or 61. In the interview report, the Examiner notes that thickeners are mentioned in the prior art. Applicant respectfully submits that even if thickeners are mentioned to thicken the composition, there is no teaching of adhesion promoting agent anywhere in the cited references. For example, Show Denko KK JP 62096408 discusses "toothpaste, chewing gum and troches". An adhesion promoter will have possibly the opposite effect that Show Denko KK JP 62096408 desires. The teaching of thickeners in the reference is thus teaching away from the present invention of claims 55 and 61.

Therefore, claims 1, 55 and 61 are patentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518.

Claims 2-5, 7, 11-12, 16-35, 37-39, 41-43, 45- 46, and 56-60 are dependent from claims 1 and 55, respectfully and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko KK in view of Pera and Parran. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that this rejection is moot in view of the remarks made in connection with independent claims 1, and 55. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features which further distinguish them from the cited references. Therefore, dependent claims 2-5, 7, 11, 12, 16-35, 37-39, 41-43, 45, 46 and 56-60 are also in condition for allowance.

Applicant respectfully submits that claims 62-63 are also in condition for allowance for at least the same reasons as noted for claim 61.

Applicant respectfully requests that the rejection of claims 1-5, 7, 11, 12, 16-35, 37-39, 41-43, 45,46 and 55-60 under 35 U. S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,755,525 and Parran et al. U.S. Patent No. 4684518 be withdrawn. Reconsideration is respectfully requested.

II. Rejections under 35 U.S.C. § 112- second paragraph

Claims 35, 39, 43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 35 recites the broad recitation “wherein the anticaries agent comprises from about

0.1% to about 4% by weight of the composition”, and the claim also recites “or from about 0.2% by weight to about 0.8%” which is the narrower statement of the range/limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 39 recites the broad recitation “wherein the antimicrobial agent comprises from about 0.01% to about 2% by weight of the composition”, and the claim also recites “or from about 0.1% to about 1% by weight of the composition” which is the narrower statement of the range/limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad

language is followed by such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 43 recites the broad recitation “wherein the desensitizing agent comprises potassium nitrate in an amount of from about 3% to about 6% by weight of the composition”, and the claim also recites “or in an amount of about 5% by weight of the composition” which is the narrower statement of the range/limitation.

Applicant respectfully traverses the rejection.

Claims 35, 39 and 43 are presented in what Applicant believes to be a correct Markush format, comprising one range of values or another range of values. However, in the interest of advancing prosecution, Applicant has deleted one range of values from each of these claims. The rejection is therefore mooted.

As for claim 46, Applicant respectfully submits that there is nothing improper in claiming that n is any number between 2 and 10. The claim is also not in a Markush format.

Reconsideration is respectfully requested.

CONCLUSION

In view of the remarks provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims: 1-5, 7, 11-13, 16-35, 37-39, 41-43, 45-46, and 55-63.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-621-6415.

Dated: June 10, 2008

Respectfully submitted,

_____/Nancy N. Quan/

Nancy N. Quan

Reg. 36, 248

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